



# THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for:

Samuel C. Wadsworth et al.

Examiner: Not Assigned

Serial No.: 10/656,474

Group Art Unit: 3736

Filing Date: September 4, 2003

For: **IMPROVED AAV VECTORS FOR GENE THERAPY**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

CERTIFICATE OF MAILING: Date of Deposit: *Jan. 20, 2004*

I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313

*MICHELE SILVER*

Printed name of person mailing correspondence

*Michele Silver*

Signature of person mailing correspondence

## INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

### I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement is filed:

- With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).
- Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.
- Before the mailing date of a first Office Action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for any fees required pursuant to 37 C.F.R. §§ 1.17(p) or 1.17(i)(1).

This Information Disclosure Statement is filed:

- After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever comes first, and the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for the fee (\$180.00) set forth in 37 C.F.R. § 1.17(p) and any additional required fees.

This Information Disclosure Statement is filed:

- After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

The undersigned certifies that:

- Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56 more than three months prior to the filing of this Information Disclosure Statement.

## **II. Copies of the Cited Items:**

- Copies of all of the items listed on the attached Form PTO-1449 are enclosed.
- Copies of only the following items listed on the attached Form PTO-1449 are not enclosed: 5,168,062 Stinski; 5,436,146 Shenk et al.; 5,872,005 Wang et al.; 6,004,797 Colosi; 6,040,183 Ferrari et al.

- Copies of those items which are marked with an asterisk (\*) in the attached Form PTO-1449 are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application No. \_\_\_\_\_ filed \_\_\_\_\_ and relied upon in this application for an earlier filing date under 35 U.S.C. § 120. See 37 C.F.R. § 1.98(d).
- Copies of those items which are marked with an asterisk (\*) in the attached Form PTO-1449 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

### **III. Concise Explanation of Relevance:**

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

The Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for any additional fees required in connection with the filing of this Information Disclosure Statement.

1/20/04

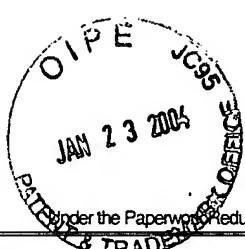
Date

Respectfully submitted,

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

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of

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Complete if Known	
Application Number	10/656,474
Filing Date	September 4, 2003
First Named Inventor	Samuel C. Wadsworth et al.
Group Art Unit	3736
Examiner Name	Not Assigned
Attorney Docket Number	GEN5-7.1CON

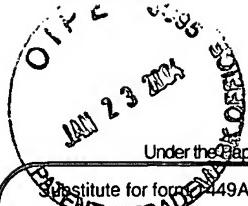
OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	12	*CLARK, R.K. et al., Cell Lines for the Production of Recombinant Adeno-Associated Virus, Human Gene Therapy, Vol. 6, October 1995, pp. 1329-1341; Mary Ann Liebert, Inc.	
	13	*FLOTTE, T.R. et al., An Improved System for Packaging Recombinant Adeno-Associated Virus Vectors Capable of In Vivo Transduction, Gene Therapy, Vol. 2, January 1995, pp. 29-37; Stockton Press	
	14	KOTIN, R.M. et al., Characterization of a Preferred Site on Human Chromosome 19q for Integration of Adeno-Associated Virus DNA by Non-Homologous Recombination, The Embo Journal, Vol. 11, No. 13, 1992, pp. 5071-5078	
	15	ROLLING, F. et al., AAV as a Viral Vector for Human Gene Therapy, Molecular Biotechnology, Vol. 3, 1995, pp. 9-15; Humana Press, Inc.	
	16	WALSH, C.E. et al., Regulated High-Level Expression of a Human Gamma-Globin Gene Introduced into Erythroid Cells by an Adeno-Associated Vector, Proceedings to the National Academy of Sciences, Vol. 89, No. 15, August 1, 1992, pp. 7257-7261; Medical Sciences	
	17	WEITZMAN, M.D. et al., Adeno-Associated Virus (AAV) Rep Proteins Mediate Complex-Formation Between AAV DNA and Its Integration Site in Human DNA, Proceedings of the National Academy of Sciences, Vol. 91, No. 13, June 12, 1994, pp. 5808-5812, Biochemistry	
	18	XIAO, X. et al., Adeno-Associated Virus (AAV) Vectors for Gene Transfer, Advanced Drug Delivery Reviews, Vol. 12, 1993, pp. 201-215; Elsevier Science Publishers B.V.	
	19	ZHOU, S.Z. et al., Adeno-Associated Virus 2-Mediated Transduction and Erythroid Cell-Specific Expression of a Human Beta-Globin Gene; Gene Therapy, Vol. 3, March 1996, pp. 223-229; Stockton Press	

Examiner Signature	Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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<p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p> <p>Sheet <b>1</b> of <b>2</b></p>		<p><b>Complete if Known</b></p> <table border="1"> <tr> <td>Application Number</td> <td>10/656,474</td> </tr> <tr> <td>Filing Date</td> <td>September 4, 2003</td> </tr> <tr> <td>First Named Inventor</td> <td>Samuel C. Wadsworth et al.</td> </tr> <tr> <td>Art Unit</td> <td>3736</td> </tr> <tr> <td>Examiner Name</td> <td>Not Assigned</td> </tr> <tr> <td>Attorney Docket Number</td> <td>GEN5-7.1CON</td> </tr> </table>		Application Number	10/656,474	Filing Date	September 4, 2003	First Named Inventor	Samuel C. Wadsworth et al.	Art Unit	3736	Examiner Name	Not Assigned	Attorney Docket Number	GEN5-7.1CON
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## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
6		*WO95/14771	06-01-95	Kotin et al.		
7		*WO96/15777	05-30-96	Wiener et al.		
8		*WO96/18727	06-20-96	Natsoulis et al.		
9		*EPO 592836	04-20-94	Kotin et al.		
10		*CA 2,205,874	05-30-96	Wiener et al.		
11		*CA 2,206,244	06-20-96	Natsoulis et al.		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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